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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,567	09/19/2005	Peter Mullejans	P70821US0	9658
136	7590	10/12/2006	EXAMINER	
JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			HAND, MELANIE JO	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/549,567	Applicant(s) MULLEJANS ET AL.	
	Examiner Melanie J. Hand	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/6/06</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Acknowledgment is also made of applicant's claim for priority under 35 U.S.C. 371 claiming benefit of copending Application No. PCT/DK04/00157, filed on March 12, 2004.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 6, 2006 was filed after the mailing date of the Application on September 19, 2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolrich (U.S. Patent No. 5,423,782).

With respect to **Claims 1,7,13**: Wolrich teaches an ostomy appliance comprising base plate 14 having a first hole and adhesive wafer 20 having a first surface to be attached to a wearer, a bag 12 releasably attached to said base plate, wherein the bag has a second hole for receiving waste and disposable inner bag liner 38 having a third hole 50 for receiving waste. The inner bag liner 38 is releasably attachable to base plate 14 in a first coupling area by first coupling means 26, and bag 12 is releasably attachable to base plate 14 by second coupling means 18. First coupling means 26 comprises flange 46 projecting from the rim of said third hole having a first surface for releasable sealing against a second surface of base plate 14 facing away from the user.

Wolrich teaches that flange portion 46 allows bag liner 38 to be coupled to first coupling means 18 in a fluid-tight relationship, but does not teach that flange 46 is an adhesive flange. It would be obvious to one of ordinary skill in the art to employ adhesive as opposed to the friction fit taught by Wolrich to couple the flange 46 to the first coupling means and thus to the base plate via adhesives with a reasonable expectation of success as hydrophobic adhesives are well-known in the art for their use in joining ostomy bags to securing members, thus also achieving a fluid-tight relationship.

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With respect to **Claim 2**: Wolrich teaches that second coupling means 18 also employs a friction fit via ring and groove portions 34 and 36, and therefore does not teach that second coupling means is an adhesive flange. It would be obvious to one of ordinary skill in the art to employ adhesive as opposed to the friction fit taught by Wolrich to couple the second coupling means 18 to the base plate via adhesives with a reasonable expectation of success as hydrophobic adhesives are well-known in the art for their use in joining ostomy bags to securing members.

With respect to **Claim 3**: Bag 12 and bag liner 38 are joined together at third hole 50 and first coupling means 46 extends beyond the rim of third hole 50 whose diameter is equal to the inner diameter of second coupling means 18, therefore the outer diameter of first coupling means 46 is greater than the inner diameter of second coupling means 18.

With respect to **Claim 4**: Wolrich does not teach adhesives for the first and second coupling means and therefore does not teach relative peel strengths. Since the proper operation of the device depends upon the ability of the liner to be pulled out for disposal without rendering the reusable outer bag 12 unusable, i.e. the second coupling means must disengage before the first coupling means to allow the bag 12 to be pulled back for the liner 38 to be replaced and prevent waste from prematurely exiting the liner and staining the reusable bag, it would be obvious to one of ordinary skill in the art to employ adhesives as an alternate securing means to the friction fit taught by Wolrich, such that a relation exists between the peel strength of the first coupling means and second coupling means wherein the peel strength of the adhesive of the first means is stronger than the peel strength of the adhesive of the second means.

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With respect to **Claim 5**: Second coupling means is comprised of ring-shaped flange coupling 18 that mates with ring 34, therefore the second coupling means is in the form of one or more coupling rings. As can be seen in Fig. 1, the outer diameter of first coupling means 46 is less than the inner diameter of first coupling means 18.

With respect to **Claims 6,14**: Bag liner 38 is vapor permeable but liquid-impermeable, which allows intestinal gas to escape but is impermeable to liquids.

With respect to **Claim 8**: As can be seen in Fig. 6, the bag liner 38 is compacted lengthwise to form a disc-like structure having an outer diameter 44 that is less than the inner diameter of first coupling means 46.

With respect to **Claim 9**: Fig. 4 shows that inner bag liner 38 is provided with folding lines that coincide with tapered edges 76,78.

With respect to **Claims 10,11**: Folding at the tapered edges 76,78 forms a bellows. The folding along the tapered edges 76,78 facilitates lengthwise compaction of the bag liner 38, the bellows is considered herein to be a telescopic bellows.

With respect to **Claim 12**: Wolrich does not teach that the closed end of the compacted bag liner 38 is provided with a cover, however it would be obvious to one of ordinary skill in the art to provide a cover at least temporarily until the compacted end is covered by a stoma and the adjacent skin surface to prevent contamination of the bag and/or stoma site.

With respect to **Claim 15**: Wolrich teaches an ostomy appliance comprising base plate 14 having a first hole and adhesive wafer 20 having a first surface to be attached to a wearer, a bag 12 releasably attached to said base plate, wherein the bag has a second hole for receiving waste and disposable inner bag liner 38 having a third hole 50 for receiving waste. As can be seen in Fig. 6, the bag liner 38 is capable of being compacted lengthwise to form a disc-like structure having an outer diameter 44 that is less than the inner diameter of first coupling means 46. The inner bag liner 38 is releasably attachable to base plate 14 in a first coupling area by first coupling means 26, and bag 12 is releasably attachable to base plate 14 by second coupling means 18. First coupling means 26 comprises flange 46 projecting from the rim of said third hole having a first surface for releasable sealing against a second surface of base plate 14 facing away from the user.

Wolrich teaches that flange portion 46 allows bag liner 38 to be coupled to first coupling means 18 in a fluid-tight relationship, but does not teach that flange 46 is an adhesive flange. It would be obvious to one of ordinary skill in the art to employ adhesive as opposed to the friction fit taught by Wolrich to couple the flange 46 to the first coupling means and thus to the base plate via adhesives with a reasonable expectation of success as hydrophobic adhesives are well-known in the art for their use in joining ostomy bags to securing members, thus also achieving a fluid-tight relationship.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

MJH
September 16, 2006

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

